



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

TECH CENTER 1600/2900

SEP 26 2003

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In re Patent Application of)

Kenneth C. CUNDY et al.)

Application No.: 09/974,768)

Filed: October 9, 2001)

For: BILE-ACID CONJUGATES FOR)
PROVIDING SUSTAINED)
SYSTEMIC CONCENTRATIONS)
OF DRUGS)

Group Art Unit: 1616

Examiner: Barbara P. Badio

Confirmation No.: 6895

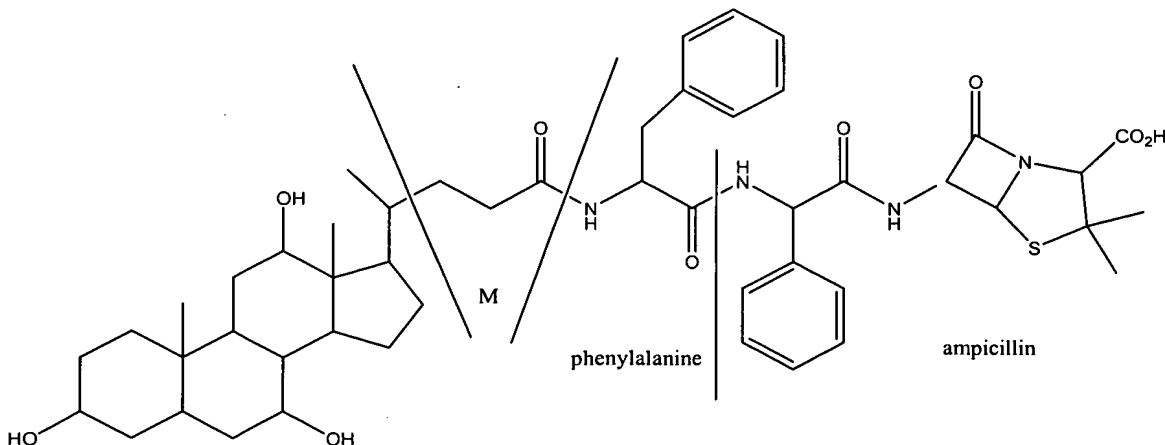
RESPONSE TO OFFICE COMMUNICATION

Assistant Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

In complete response to the Office Communication of July 21, 2003 and further to the Office Communication of September 5, 2003, Applicants submit the following response.

In order to comply with the requirements of 37 C.F.R. § 1.143, Applicants elected in their previous response a single **disclosed** species for examination. Applicants maintain their previous election, with traverse, of the following compound of formula I:



In the elected compound of formula I, X, R¹, and R² are hydroxy; Z is a group of the formula –M-Q^{x'}; M is –CH₂CH₂C(O)–; Q^{x'} is of the structure –A^{x'}-D'; A^{x'} is derived from an α-amino acid; and D' is a drug (as disclosed on page 82, lines 13-20). Alpha amino acids are taught on page 33, line 18 – page 34, line 2 and on page 35, lines 1-7). On page 35, line 6, phenylalanine is specifically disclosed as a suitable α-amino acid and phenylalanine is illustrated as a suitable α-amino acid in Figure 4. Suitable drugs D' are taught on page 35, line 23 – page 37, line 11. Ampicillin is specifically disclosed as a suitable drug D' on page 36, line 15.

Since all component substituents/pieces of the elected compound of formula I (as illustrated above) are specifically disclosed in the specification, Applicants respectfully submit that the elected compound is in fact disclosed by the present application.

As required according by 37 C.F.R. § 1.53(b), to be complete, a nonprovisional application requires a specification as prescribed by 35 U.S.C. 112 containing a description pursuant to § 1.71, at least one claim pursuant to § 1.75, and any drawing required by § 1.81(a) filed in the Patent and Trademark Office. (MPEP § 506 Completeness of Original Application). Accordingly, examples are not required for a complete application. Applicants respectfully assert that it is a well-established principle that “[t]he specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970). Therefore, to be complete an application does not require examples, and as such, exemplary compounds.

Since an application does not require examples and as such, exemplary compounds, Applicants respectfully submit that election of a *single disclosed* species *cannot* mean a *single exemplified* species. If a single disclosed species meant an exemplified species, it would be impossible to make a proper election of species in an application, which had no examples, even though it would be considered to be a complete application. Applicants further respectfully submit that the MPEP recites that an Applicant may be required under 35 U.S.C. § 121 to elect a single *disclosed* species for examination. (MPEP § 809.02(a), emphasis added). Accordingly, the MPEP does not purport to require election of a single exemplified species. In addition, the MPEP recognizes that there are instances in which there are no species in distinct figures or

examples. In this regard the MPEP states that while it is preferred that species are identified as the species of figures 1, 2, and 3 or the species of examples I, II, and III, “[i]n *the absence of distinct figures or examples* to identify the species, the mechanical means, the particular material, or *other distinguishing characteristics of the species* should be stated for each species identified.” (MPEP § 809.02(a), emphasis added).

Therefore, Applicants respectfully submit that it is not required that the elected species be illustrated as a figure or exemplified in an example or that the compound be disclosed as a complete entity at a particular location within the application. It is only required that the distinguishing characteristics of the species be stated and disclosed. Applicants respectfully submit that the present specification does, in fact, disclose all of the component substituents/pieces of the elected compound of formula I, as set forth above. Applicants also respectfully submit that the present specification further discloses a representative synthesis of the elected compound of formula I. Accordingly, even though the elected compound is not exemplified in a particular Example or illustrated in a Figure, the compound of formula I as elected is disclosed by the present application.

Applicants further note that the specification of the present application states that [t]he following examples illustrate how the synthesis of GABA analog conjugates could be conducted in order to prepare compounds of formula (I). It is contemplated that *other drugs* may be used in place of a GABA analog with similar synthetic schemes. The syntheses described below are illustrated in Figures 4 – 8. While *GABA is not included within the scope of this invention*, these examples are *illustrative* of how other drugs could be readily coupled to a bile acid in an analogous manner.

Page 90, lines 4-10, emphasis added. Accordingly, it is inappropriate for the Examiner to refuse to accept Applicants' elected compound of formula I and examine the claims in light of that election.

As set forth in the Response filed on June 6, 2003, it is believed that claims 1, 3, 4, 6, 8 – 10, 12, 13, 15, 17, 18, 20, and 23 are readable upon the elected species as defined above. Applicants have no intention of abandoning any non-elected subject matter and expressly reserve the right to file one or more continuation and/or divisional applications directed to the non-elected subject matter.

Applicants further specifically reserve their right under 37 C.F.R. § 1.144 to petition the Commissioner from the present requirement for restriction after it is made final.

Further in support of their position that a disclosed species does not necessarily need to be an exemplified species, Applicants respectfully submit that the MPEP addresses instances in which applications contain no working examples with regard to compliance with the enablement requirement of 35 § U.S.C. 112, first paragraph. As recited in the MPEP, “[c]ompliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed. An example may be ‘working’ or ‘prophetic.’ A working example is based on work actually performed. A prophetic example describes an embodiment of the invention based on predicted results rather than work actually conducted or results actually achieved.” (MPEP § 2164.02 Working Example).

Accordingly, Applicants respectfully submit that it is improper to maintain the position that Applicants have failed to respond fully to the outstanding Office Action as Applicants have elected a single, disclosed species, even though it is not exemplified. Applicants respectfully submit that the elected compound of formula I should be examined and if believed to be appropriate, the proper rejection at this point in prosecution would be a rejection under 35 § U.S.C. 112. If and when such a rejection is made, Applicants will respond in an appropriate manner.

Patent Term Adjustment and Request for Refund for Petition for Extension of Time

Applicants respectfully assert that delays in processing of the present application caused by Applicants’ alleged not fully-responsive election of species should not be held against Applicants, as Applicants did fully respond in their initial response filed on June 6, 2003 with a two-month extension of time. Accordingly, Applicants expressly reserve their right to request reconsideration of any patent term adjustment determination, which reduces the patent term for the period in which Applicants were alleged to have filed incomplete election of species responses.

Applicants also request refund of the one-month extension of time fee filed herewith, as required by the Office Communication of September 5, 2003 to respond to the Office

Communication of July 21, 2003. Applicants respectfully assert that the response filed on June 6, 2003 with a two-month extension of time was fully responsive to the Office Action of April 19, 2003. Applicants further respectfully assert that the response filed on August 21, 2003 was fully responsive to the Office Communication of July 21, 2003, alleging that Applicants' original response was incomplete. Applicants file herewith a second fully responsive reply to the Office Communication of July 21, 2003, with one-month extension of time. As the original responses filed on June 6, 2003 and August 21, 2003 were fully responsive, the present extension of time should not be required. Accordingly, Applicants request a refund in the amount of \$ 110.00 in connection with the above-identified application be made to Deposit Account No. 02-4800.

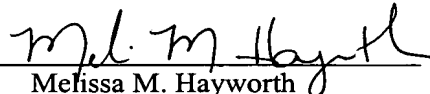
Conclusion

In view of the foregoing remarks, reconsideration of the claims is earnestly solicited. The Examiner is invited to contact the undersigned at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By



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(703) 836-6620

Dated: September 22, 2003



Attorney Docket No. 1616 Patent 033053-040

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Kenneth C. CUNDY et al.

Application No.: 09/974,768

Filing Date: October 9, 2001

Title: BILE-ACID CONJUGATES FOR PROVIDING SUSTAINED SYSTEMIC CONCENTRATIONS OF DRUGS

Group Art Unit: 1616

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TECH CENTER 1610/2900

SEP 26 2003

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AMENDMENT/REPLY TRANSMITTAL LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Enclosed is a reply for the above-identified patent application.

☒ A Petition for Extension of Time is also enclosed.

☐ Terminal Disclaimer(s) and the ☐ \$55.00 (2814) ☐ \$110.00 (1814) fee per Disclaimer due under 37 C.F.R. § 1.20(d) are also enclosed.

☐ Also enclosed is/are _____

☐ Small entity status is hereby claimed.

☐ Applicant(s) requests continued examination under 37 C.F.R. § 1.114 and enclose the ☐ \$375.00 (2801) ☐ \$750.00 (1801) fee due under 37 C.F.R. § 1.17(e).

☐ Applicant(s) requests that any previously unentered after final amendments not be entered. Continued examination is requested based on the enclosed documents identified above.

☐ Applicant(s) previously submitted _____

_____ on _____
for which continued examination is requested.

☐ Applicant(s) requests suspension of action by the Office until at least _____ which does not exceed three months from the filing of this RCE, in accordance with 37 C.F.R. § 1.103(c). The required fee under 37 C.F.R. § 1.17(i) is enclosed.

☐ A Request for Entry and Consideration of Submission under 37 C.F.R. § 1.129(a) (1809/2809) is also enclosed.

- ☒ No additional claim fee is required.
- ☐ An additional claim fee is required, and is calculated as shown below.

AMENDED CLAIMS					
	No. of Claims	Highest No. of Claims Previously Paid For	Extra Claims	Rate	Additional Fee
Total Claims		MINUS =	0	x \$18.00 (1202) =	\$ 0.00
Independent Claims		MINUS =	0	x \$84.00 (1201) =	\$ 0.00
If Amendment adds multiple dependent claims, add \$280.00 (1203)					
Total Claim Amendment Fee					\$ 0.00
<input type="checkbox"/> Small Entity Status claimed - subtract 50% of Total Claim Amendment Fee					\$ 0.00
TOTAL ADDITIONAL CLAIM FEE DUE FOR THIS AMENDMENT					\$ 0.00

- ☐ A total fee in the amount of _____ is enclosed.
- ☒ Charge \$ 110.00 to Deposit Account No. 02-4800.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17, 1.20(d) and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

BURNS, DOANE, SWÉCKER & MATHIS, L.L.P.

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Date: September 22, 2003

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